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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,622	06/19/2006	Thomas Nissl	NISSL-2	8513

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EXAMINER

STEWART, JASON-DENNIS NEILKEN

ART UNIT	PAPER NUMBER
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3738

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04/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/596,622	Applicant(s) NISSL, THOMAS	
	Examiner JASON-DENNIS STEWART	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9, 10 and 12-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9, 10, and 12-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04 February 2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The following is a Final Office action in response to communications received on 01/05/2009. Claim 11 has been cancelled. Claims 9 and 15 have been amended. Therefore, Claims 9, 10, and 12-18 are currently pending and addressed below.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 15 recites a widened head "facing away" from a tie bar. It is unclear which way Applicant is suggesting a head portion of two connected struts would face, let alone what would be considered "facing away". Examiner has examined the claim as best understood.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 9, 10, 12, 13, and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaeffer 6,786,922, in view of Lootz et al. 2002/004987 further in view of Schaeffer 2005/0222670.

5. Regarding claim 9, Schaefer '922 discloses a stent 10 for application in a body vessel, comprising a tubular support frame made of plural ring segments 12, which are arranged sequentially in an axial direction and formed by struts 16, 18, 20, and adjoin each other continuously via transitions 24, with each strut defined by a longitudinal strut axis, the support frame further including first and second tie bars 14 for connecting neighboring ring segments 12, each of the tie bars including an arm 38 extending in circumferential direction of the support frame and terminating on both ends in axial sections 14 for connection of the first and second ties bars to the transitions 24, wherein the axial sections of the first tie bars define a longitudinal axis (figs. 1, 4). However, Schaefer does not teach that the struts have a wavy configuration and a width which as measured transversely to the longitudinal strut axis increases from midsection in a direction to the transitions, or that the tie bars are of wavy configuration and have a width which as measured transversely to the longitudinal axis that increases from the arm in a direction to the transitions.

Lootz teaches a stent, in the same field of endeavor, with bars 3" having a longitudinal axis, a wavy configuration, and a width that increases from the midsection 16 in a direction to the transition 3.1" for the purpose of improving stress distribution as the shape memory stent self-expands (par. 77-81; fig. 5).

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It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the straight struts and tie bars of the uniform width disclosed by Schaeffer '922 to include a wavy configuration with a width increasing from a midsection to a transition as taught by Lootz in order to allow a stent formed from a shape memory material like Nitinol, which Schaeffer '922 discloses (col. 5, ll. 1-4) to transition into a stress-induced state as the stent self expands below the plastic deformation limit providing better stress distribution and less chance of failure.

Schaeffer '922 in view of Lootz discloses the invention as claimed and as discussed above. However, although implied, Schaeffer '922 in view of Lootz does not positively disclose "bars extending from a bottom of two interconnected struts of a ring segment to an opposing bottom of two interconnected struts of an adjacent ring segment". It should be noted, that such a limitation is highly ambiguous in nature. The terms "top" and "bottom" do not identify a particular configuration of the stent or its structure because these terms can be interpreted merely based on the location and placement of the device.

Schaeffer '670 discloses a stent in which "bottoms" of connecting struts are attached to opposing "bottoms" of different sets of connecting struts (Fig. 4)

It would have obvious to one of ordinary skill in the art to modify the device of Schaeffer '922 in view of Lootz with the connecting strut design of Schaeffer '670 in order to reduce the profile of a stent with adjacent unit structures as taught by Schaeffer '670 (paragraph 27).

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6. Regarding Claims 10, 12, and 13, Schaeffer '922 discloses arms and bars arranged between offset stent segments where a bar extends from the tip of two interconnected struts of a ring segments to the struts of an adjacent segment (figs. 1-4).

7. Regarding claims 16-18, Lootz discloses struts with increased wave radii and struts that get wider at the ends of the strut (Fig. 5, paragraphs 78 and 81).

8. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaeffer 6,786,922 in view of Lootz et al. 2002/0049487 in view of Schaeffer 2005/0222670 as applied to Claim 9 above, and further in view of Bales et al. 6,878,162.

9. Schaeffer '922 in view of Lootz in view of Schaeffer '670 discloses the invention as claimed and as discussed above, but does not disclose that each third of the transitions has an end formed with a widened head which protrudes in the axial direction neighboring ones of the transitions.

Bales discloses a stent, wherein each third of the transitions 36 has a widened head 37 for the purpose of receiving a radiopaque marker (fig. 1; col. 4, ll. 28-31).

It would have been obvious to one of ordinary skill in the art at the time of the invention to include a widened head for radiopaque markers as taught by Bales on the stent of Schaeffer '922 in view of Lootz in view of Schaeffer '670 in order to attach markers at the end which allows a surgeon to visualize the stent while it is being deployed as well as after placement.

Regarding Claim 15, Schaeffer '670 discloses a widened head connected to a connection point formed by a tie bar and two connected struts and facing away from a tie bar (fig. 4).

Response to Arguments

10. Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON-DENNIS STEWART whose telephone number is (571)270-3080. The examiner can normally be reached on M-F (alt Fridays off) 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jason-Dennis Stewart/
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738

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